15 December 2011
EMA/679632/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Esmya

ulipristal acetate

On 15 December 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Esmya, 5mg, tablet, intended for pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to 3 months.

The applicant for this medicinal product is PregLem France SAS. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Esmya is ulipristal acetate, a selective progesterone receptor modulator, characterised by a tissue-specific partial progesterone antagonist effect. It acts by depriving uterine fibroids of growth stimulation due to progesterone.

The treatment consists of one tablet of 5 mg to be taken orally once daily for up to 3 months, and it should be started during the first week of a menstrual cycle. There are no data available on treatment with a duration longer than 3 months or on repeat courses of treatment. Therefore, treatment duration should not exceed 3 months.

The benefits with Esmya are its ability to reduce fibroid-related bleeding, anaemia and fibroid size. Ulipristal showed better efficacy compared to placebo (a dummy) at reducing bleeding and anaemia, and fibroid volume.

The most common side effects are amenorrhea, endometrial thickening and hot flush.

A pharmacovigilance plan for ulipristal will be implemented as part of the marketing authorisation.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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The approved indication is: "Ulipristal acetate is indicated for pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to 3 months (see section 4.4)".

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Esmya and therefore recommends the granting of the marketing authorisation.